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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/559,784 | 12/08/2005 | Mitsuko Kosaka | 64603(70904) | 8189 |
| 21874 7590 09/25/2008 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 POSTON, MA 02205 | | | EXAMINER | |
| | | | DUTT, ADITI | |
| BOSTON, MA 02205 | | | ART UNIT | PAPER NUMBER |
| | | | 1649 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 09/25/2008 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | | |
|--|---|--|--|--|
| | 10/559,784 | KOSAKA, MITSUKO | | |
| Office Action Summary | Examiner | Art Unit | | |
| | Aditi Dutt | 1649 | | |
| The MAILING DATE of this communication ap Period for Reply | pears on the cover sheet with the c | correspondence address | | |
| A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING D - Extensions of time may be available under the provisions of 37 CFR 1. after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period - Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailin earned patent term adjustment. See 37 CFR 1.704(b). | DATE OF THIS COMMUNICATION 136(a). In no event, however, may a reply be tirwill apply and will expire SIX (6) MONTHS from e, cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). | | |
| Status | | | | |
| Responsive to communication(s) filed on <u>27 F</u> This action is FINAL . 2b) ☑ This Since this application is in condition for allowated closed in accordance with the practice under Expression in the | s action is non-final. ance except for formal matters, pro | | | |
| Disposition of Claims | | | | |
| 4) Claim(s) <u>1-14</u> is/are pending in the application 4a) Of the above claim(s) is/are withdra 5) Claim(s) is/are allowed. 6) Claim(s) is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) <u>1-14</u> are subject to restriction and/or | awn from consideration. | | | |
| Application Papers | | | | |
| 9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) acc Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the E | cepted or b) objected to by the drawing(s) be held in abeyance. Section is required if the drawing(s) is ob | e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d). | | |
| Priority under 35 U.S.C. § 119 | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail Di 5) Notice of Informal F 6) Other: | ate | | |

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DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5, drawn to a method for producing retinal nerve cells by co-culturing embryonic retinal stem cells and iris pigmented epithelial cells.

Group II, claim(s) 6, 13 and 14, drawn to retinal nerve cells.

Group III, claim(s) 7-10, drawn to a method for producing retinal nerve cells by isolating and differentiating iris pigmented epithelial cells in a serum free culture medium.

Group IV, claim(s) 11-12, drawn to a method for producing retinal nerve cells by isolating and culturing iris pigmented epithelial cells in a serum free culture medium, and inducing differentiation in the presence of serum in the medium.

2. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I recites the special technical feature for producing retinal stem cells by coculturing embryonic retinal stem cells and iris pigmented epithelial cells, which is not required by the other methods of Groups III-IV or the product of Group II.

Group II recites the special technical feature of retinal nerve cells, which is not required by the methods of Groups I and III-IV.

Group III recites the special technical feature of for producing retinal nerve cells by isolating and differentiating iris pigmented epithelial cells in a serum free culture

medium, which is not required by the other methods of Groups I and IV or the product of Group II.

Group IV recites the special technical feature of producing retinal nerve cells by isolating and culturing iris pigmented epithelial cells in a serum free culture medium, and inducing differentiation in the presence of serum in the medium, which is not required by the other methods of Groups I and III or the product of Group II.

3. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

- 4. In response to this Office Action/Election requirement, applicant must elect one from Groups I-IV, for consideration.
- 5. Applicant is advised that in order for the reply to this requirement to complete it must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

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6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the required under 37 C.F.R. 1.17(l).

Notice of Rejoinder

- 7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.
- 8. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to

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be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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Advisory Information

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aditi Dutt whose telephone number is 571-272-9037. The examiner can normally be reached on M-F.

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10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

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supervisor, Jeffrey Stucker can be reached on 571-272-0911. The fax phone number

for the organization where this application or proceeding is assigned is 571-273-8300.

11. Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AD

15 September 2008

/Jeffrey Stucker/

Supervisory Patent Examiner, Art Unit 1649